OLR Bill Analysis

sSB 152

AN ACT CONCERNING THE ESTABLISHMENT OF THE CONNECTICUT UMBILICAL CORD BLOOD COLLECTION BOARD.

SUMMARY:

This bill creates the "Connecticut Umbilical Cord Blood Collection Board," charged with establishing a state umbilical cord blood collection program. Board members are appointed by the governor and legislative leaders and include the Department of Public Health (DPH) commissioner.

The umbilical cord blood collection program must promote the collection of umbilical cord blood units from genetically diverse donors for public use. The board may raise funds and apply for and accept any public or private grant money. The board, based on the funding available, must contract with entities that have expertise in collecting and transporting umbilical cord blood units to establish or designate at least two collection centers in the state. The board, subject to appropriations, must engage in public education and marketing activities concerning cord blood.

The bill establishes a separate, nonlapsing General Fund account for this program. It also establishes auditing and reporting requirements.

EFFECTIVE DATE: Upon passage

CONNECTICUT UMBILICAL CORD BLOOD COLLECTION BOARD Board Members

The bill establishes an eight member Connecticut Umbilical Cord Blood Collection Board which is not a department, institution, agency or political subdivision of the state. Board members are as follows:

1. one appointed by the governor, who is a medical director or chief scientist with knowledge of umbilical cord blood banking and affiliated with an entity that is recognized by DPH;

- 2. one appointed by the House speaker, who is a licensed physician with experience in transplanting units of umbilical cord blood or other stem cells;
- 3. one appointed by the Senate president pro tempore, who is a licensed physician who (a) has expertise and is currently practicing in obstetrics at a birthing hospital that participates in umbilical cord blood collection and (b) is affiliated with a private university hospital;
- 4. one appointed by the House majority leader, who is a licensed physician who (a) has expertise and is currently practicing in obstetrics at a birthing hospital that participates in umbilical cord blood collection, and (b) is affiliated with a public university hospital;
- 5. one appointed by the House minority leader, who is a licensed physician who has expertise and is currently practicing in obstetrics at a birthing hospital that participates in umbilical cord blood collection;
- 6. one appointed by the Senate majority leader, who is a member of a nonprofit umbilical cord blood foundation with knowledge of umbilical cord blood banking issues;
- 7. one appointed by the Senate minority leader, who has expertise concerning the regulatory practices of the federal Food and Drug Administration (FDA) and the federal Health Resources and Services Administration; and
- 8. the DPH commissioner, or her designee.

Appointment Terms

All initial board appointments must be made by October 1, 2011. The governor's appointee serves at his pleasure but not longer than his term of office or until the member's successor is appointed and has

qualified, whichever term is longer. Each legislator-appointed board member serves at the pleasure of the appointing authority. The appointing authority must fill any vacancy for the unexpired term of a member he or she appoints. Any member can be reappointed.

The governor appoints the board chairperson from the board members. The chairperson must schedule the first meeting, which must held by November 1, 2011. Afterwards, board meetings must be held quarterly and at other times the chairperson deems necessary.

Appointed members cannot designate anyone to represent them in their absence. Any appointed member who misses three consecutive meetings or 50% of all meetings held during any calendar year is considered to have resigned. The appointing authority may remove a member for inefficiency, neglect of duty, or misconduct in office after giving the member a written copy of the charges against the member and an opportunity to be heard, in person or by counsel, in the member's defense, with not less than 10 days' notice. If any member is removed in this manner, the appointing authority must file with the secretary of the state (1) a complete statement of charges made against the member, (2) the appointing authority's findings on the statement of charges, and (3) a complete record of the proceedings.

Transacting Business

A quorum is five members. In order to transact any business or exercise any powers, the board may act by a majority of the members present at any meeting at which a quorum is present.

The board may consult with public or private parties it considers desirable in exercising its duties.

The board may adopt written policies and procedures to carry out its statutory purposes.

Conflict of Interest

All members, other than the DPH commissioner, can be privately employed, or in a profession or business, subject to any applicable state or federal laws, rules, and regulations concerning regarding official ethics or conflict of interest.

The bill specifies that it is not a conflict of interest for a trustee, director, partner, or officer of any person, firm, or corporation or any individual having a financial interest in a person, firm, or corporation, to serve as a board member, provided the individual abstains from deliberation, action, or vote by the board in specific respect to such person, firm, or corporation.

UMBILICAL CORD BLOOD COLLECTION PROGRAM Purposes

The board must establish, by July 1, 2012, the umbilical cord blood collection program and administer it. The program must facilitate and promote the collection of units of umbilical cord blood from genetically diverse donors for public use. "Public use" means

- 1. use of umbilical cord blood units by state, national, and international cord blood registries and transplant centers in order to increase the likelihood of providing suitably matched donor umbilical cord blood units to patients in need of such units or research participants who are in need of a transplant,
- 2. biological research and new clinical use of stem cells derived from the blood and tissue of the umbilical cord, and
- 3. medical research that uses umbilical cord blood units that could not otherwise be used for transplantation or clinical use.

Powers

The board may raise funds, apply for and accept any public or private grant money; accept contributions; enter into contracts; and, within available resources, hire any necessary staff, including an executive director.

Contracting With Collection Centers

The board must, based on available funds appropriated for program administration, contract with one or more entities that have demonstrated competence in collecting and transporting umbilical cord blood units in compliance with all applicable federal law and who meet all other requirements of the bill. The board must contract to establish or designate at least two umbilical cord blood collection centers at fixed state locations. A location collection center must be at at a birthing hospital with 3,750 or more births per year and where a disproportionate share of such births involve women from minority populations. The board must, to the extent practicable, encourage the collection of units of umbilical cord blood at other nonfixed state locations.

Any contract must be initiated through a competitive process that identifies the best proposals submitted by applicant entities to achieve the program's collection and research objectives. It must provide that

- 1. the state retains an interest in any umbilical cord blood collected in the state commensurate with its investment in the program;
- 2. income received by the board as a result of the contract be used to ensure that the umbilical cord blood collection program is self-sustaining by July 1, 2020;
- 3. umbilical cord blood units deemed unsuitable for transplantation be returned to the state for use in biological or medical research; and
- 4. any entity the board contracts with must provide quarterly reports to the board that include information on the total number of umbilical cord blood units collected, the number of collected units suitable for transplant, the number suitable for research only, and the clinical outcomes of any transplanted units.

Reports must not include personally identifiable information.

Any entity seeking to enter into a contract with the board must, at a minimum, be in compliance with FDA requirements concerning the manufacture of clinical-grade cord blood stem cell units for clinical indications.

Any medical or research facility performing services on behalf of the board pursuant to a contract must comply with, and is subject to, state and federal law on protecting medical information and personally identifiable information contained in, or obtained through, the umbilical cord blood collection inventory.

The board is not considered a "state contracting agency," as defined in of the general statutes (CGS § 4e-1).

UMBILICAL CORD BLOOD COLLECTION ACCOUNT

The bill establishes the "Umbilical Cord Blood Collection Account" as a separate, nonlapsing General Fund account. The account may contain any moneys required or permitted by law to be deposited in it and any moneys received from any public or private contributions, gifts, grants, donations, bequests, or devises. The board may spend account funds as necessary to carry out the board's purpose.

AUDITS AND REPORTS

Board members must provide the Public Health and Appropriations committees a copy of any board audit conducted by an independent auditing firm within seven days after the board receives the audit.

By January 1, 2012, and quarterly thereafter, the board must report to the governor and the Public Health and Appropriations committees on the status and effectiveness of the Umbilical Cord Blood Collection Program.

PUBLIC EDUCATION AND MARKETING

The board must, within available appropriations, undertake public education and marketing activities that promote and raise awareness among physicians and pregnant women of the umbilical cord blood collection program.

BACKGROUND

Umbilical Cord Blood

Umbilical cord blood has stem cells that may be used to treat blood cancers, such as leukemia, myeloma and lymphoma, and inherited

immunodeficiencies and blood diseases, including sickle cell anemia, thalassemias, hemoglobinopathies, aplastic anemias, and marrow failure disrders. Cord blood is often discarded as medical waste.

COMMITTEE ACTION

Public Health Committee

Joint Favorable Substitute Change of Reference Yea 26 Nay 0 (03/07/2011)

Government Administration and Elections Committee

Joint Favorable Yea 14 Nay 0 (03/30/2011)